

46. (Twice amended) A method for enhancing the transformation ability and the viability of bacteria, said method comprising increasing the fatty acid content of the membrane of said bacteria, wherein said bacteria, after increasing their fatty acid content, exhibit an enhanced transformation ability and enhanced viability after storage at a temperature of from about +4°C to about -80°C, relative to the transformation ability and viability exhibited by said bacteria prior to increasing their fatty acid content, wherein said increasing the fatty acid content is not accomplished by growing said bacteria at a reduced temperature, relative to the temperature at which cells are grown in which the fatty acid content is not increased.

Remarks

Reconsideration of the present application is respectfully requested

I. Status of the Claims

Applicants propose to amend claims 45-47, 70 and 71. Claims 45-71 are pending in the present application.

II. Support for the Amendment and Reasons For Entry

Applicants propose to amend claims 47, 70 and 71 to correct a typographical error. Applicants propose to amend claims 45 and 46 to recite an exclusionary proviso.

No new matter will be added by the proposed amendments amendment. Entry of the proposed amendment will not raise new issues that would require further consideration and/or search. Entry of the proposed amendment will place the application in better form for

allowance or appeal. Applicants respectfully request that this amendment be considered and entered.

III. The Rejection For Alleged Obviousness-Type Double Patenting

At page 2 of the Office Action, the Examiner maintained the rejection of claims 45-69, 70 and 71 for alleged obviousness-type double patenting, over claims 1-10 and 13-16 of U.S. Patent No. 5,891,692 ("the '692 patent"). Applicants respectfully request that this rejection be held in abeyance until the remaining outstanding issues in this application are resolved. Once the remaining outstanding issues are resolved, Applicants will file a terminal disclaimer over the '692 patent.

IV. The Rejection Over Inoue Must Be Withdrawn

At page 2 of the Office Action, the Examiner maintained the rejection of claims 45-49 and 51-56, under 35 U.S.C. § 102(b), as allegedly anticipated by Inoue *et al.*, *Gene* 96: 23 (1990) ("Inoue"). Applicants respectfully traverse this rejection.

Applicants propose to amend claims 45 and 46 to recite a method for increasing both transformation ability and viability, comprising increasing the fatty acid content of the bacterial membrane, such that the bacteria exhibit an enhanced transformation ability and enhanced viability after storage at a temperature of from about +4°C to about -80°C, relative to the transformation ability and viability exhibited by the bacterium prior to increasing its fatty acid content, wherein said increasing the fatty acid content is not accomplished by growing said bacteria at a reduced temperature, relative to the temperature at which cells are grown in which the fatty acid content is not increased.

Inoue fails to teach a method of increasing the fatty acid content by any method other than growing bacteria at a reduced temperature. Accordingly, Inoue fails to teach the method of claims 45-49 and 51-56, as Applicants propose to amend the claims.

Applicants respectfully request that this rejection be reconsidered and withdrawn.

V. The Rejection Over de Mendoza II Must Be Withdrawn

A. de Mendoza II Fails To Anticipate Claims 58-69

At page 2 of the Office Action, the Examiner maintained the rejection of claims 58-69, under 35 U.S.C. § 102(b), as allegedly anticipated by de Mendoza *et al.*, *TIBS* 8: 49 (1983) ("de Mendoza II")¹. At page 4 of the Office Action, the Examiner alleged that de Mendoza II inherently anticipates claims 58-69. Applicants respectfully traverse this rejection.

Inherency "may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient." *Continental Can Co. USA, Inc. v. Monsanto Co.*, 17 USPQ2d 1746, 1749 (Fed. Cir. 1991) (citing *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981)). Here, the Examiner has not established that bacteria treated as disclosed in de Mendoza II would necessarily exhibit increased transformation ability after storage at a temperature of from about +4°C to about -20°C, as recited in claims 58 and 59, or after storage at a temperature of about -20°C, as recited in claim 71.

¹ This article by de Mendoza *et al.* was cited by the Examiner as document "X" in the PTO-892 attached to Paper No. 8. Since this article was referred to as "de Mendoza II" in the reply filed March 21, 2000, Applicants will refer to this article as de Mendoza II in the present reply.

Further, to rely on an inherency argument, "the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (PTO Bd. Pat. App. Int. 1990). Here, the Examiner has not provided any basis in fact or technical reasoning to reasonably support the allegation that bacteria treated as disclosed in de Mendoza II would exhibit increased transformation ability after storage at a temperature of from about +4°C to about -20°C, as recited in claims 58 and 59, or after storage at a temperature of about -20°C, as recited in claim 71.

At page 4 of the Office Action, the Examiner alleged that the preamble of claims 58 and 59 had been amended to recite enhanced transformation ability. Apparently implicit in the Examiner's statement is the notion that the term "enhanced transformation ability" is not recited in the body of claims 58 and 59. Applicants respectfully draw the Examiner's attention to claims 58 and 59, wherein the term "enhanced transformation ability" is recited in the body of each claim.

Inherent anticipation has not been established. de Mendoza II fails to teach the invention of claims 58-69.

C. *de Mendoza Would Not Have Suggested The Methods Of Claims 58-69*

At page 4 of the Office Action, the Examiner stated:

In the alternative, the ordinary artisan would have recognized that the benefits of using bacteria having more fluid membranes as a result of an increase of unsaturated fatty acids in said membranes for enhanced viability in transformations. The ordinary artisan would have been motivated to use these bacteria because (1) they were already known in the art to have better viability, thus would be expected to weather the transformation procedures better than

bacteria with less fluid membranes (transformation procedures were well known to even the lesser skilled artisans by the time of Applicant's invention) and (2) even intuitively, the ordinary artisan would have expected that more fluid membranes would allow a higher degree of ingress of exogenously added DNA. Thus, the invention would have been obvious over de Mendoza *et al.*

The Examiner did not formally reject claims 58-69 as allegedly obvious, under 35 U.S.C. § 103. From the Examiner's comments at page 4 of the Office Action, the Examiner is apparently of the opinion that the methods of claims 58-69 would allegedly have been inherently obvious over de Mendoza II. Applicants respectfully traverse this. There is no such thing as "inherent obviousness." *See In re Spormann and Heinke*, 150 USPQ 449, 452 (CCPA 1966) ("As we pointed out in *In re Adams*, 53 CCPA 966, 356 F.2d 998, 148 USPQ 742, the inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown.").

If, at page 4 of the Office Action, the Examiner intended to reject claims 58-69 as allegedly obvious, under 35 U.S.C. § 103, then a *prima facie* case of obviousness has not been established.

The Examiner's statements, quoted above, are conclusory and do not rise to the level of evidence required to support a *prima facie* case of obviousness. The Examiner has provided no evidence to show that one of ordinary skill in the art would have thought, based on de Mendoza II, that increasing the level of unsaturated fatty acids in bacterial cell membranes would result in an increase in transformation ability after storage at a temperature of from about +4°C to about -20°C.

Further, the Examiner has provided no evidence to show that one of ordinary skill in the art would have been motivated to modify the disclosure of de Mendoza II in an effort to obtain a method for enhancing transformation ability by increasing the level of unsaturated fatty acids in bacterial cell membranes, such that the bacteria exhibit an increase in transformation ability after storage at a temperature of from about +4°C to about -20°C.

Moreover, the Examiner has provided no evidence that one of ordinary skill in the art would have known that increasing unsaturated fatty acids would result in increased viability. Nor has the Examiner provided any evidence that one of ordinary skill in the art would have expected that more fluid membranes would allow a higher degree of ingress of exogenously added DNA.

If the Examiner's statements are based on personal knowledge known by the Examiner, the Examiner is invited to provide Applicants with an Examiner affidavit. *See* MPEP § 2144.04.

Moreover, the Examiner has failed to address each limitation of the claimed methods. Claims 58 and 59 recite that, as a result of increasing the level of unsaturated fatty acids in bacterial cell membranes, the bacteria exhibit an increase in transformation ability after storage at a temperature of from about +4°C to about -20°C. The Examiner has provided no basis as to why de Mendoza II allegedly suggests that property. Claim 71 recites that, as a result of increasing the level of unsaturated fatty acids in bacterial cell membranes, the bacteria exhibit an increase in transformation ability after storage at about -20°C. The Examiner has provided no basis as to why de Mendoza II allegedly suggests that property.

de Mendoza II fails to suggest the claimed invention

D. Summary

de Mendoza II fails to teach or suggest the methods of claims 58-69. Applicants respectfully request that this rejection be reconsidered and withdrawn.

VI. The Rejection Under 35 U.S.C. § 112, First Paragraph, Must Be Withdrawn

At page 3 of the Office Action, the Examiner maintained the rejection of claims 45-69 under 35 U.S.C. § 112, first paragraph, as allegedly not enabled. Applicants respectfully traverse this rejection.

At pages 13-20 of the reply filed March 21, 2000, Applicants provided a detailed rebuttal of the Examiner's proffered basis for this rejection. At page 5 of the Office Action, the Examiner stated "[t]here remains no clear evidence in the specification or in the prior art that a wholesale increase in both saturated and unsaturated fatty acids or saturated fatty acids alone results in increased transformation and viability "

Applicants respectfully point out that it is not Applicants' burden to prove that the full scope of each of the claimed methods is enabled. Instead, the Examiner bears the burden of establishing, by objective evidence or sound scientific reasoning, why there is reason to doubt that the claimed methods are not in compliance with the enabling requirement of 35 U.S.C. § 112, first paragraph. *See In re Cortright*, 49 USPQ2d 1464, 1466 (Fed. Cir. 1999); *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971); MPEP § 2164.04.

Here, the Examiner has provided only conclusory reasons why the claimed methods allegedly are not enabled. The Examiner has not provided any evidence or sound scientific reasoning why there is reason to doubt that the claimed methods are not in compliance with the enabling requirement of 35 U.S.C. § 112, first paragraph. Absent such evidence or sound

scientific reasoning, this rejection is improper. Applicants respectfully request that this rejection be reconsidered and withdrawn.

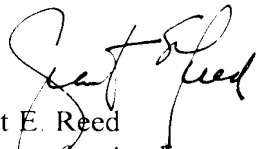
Conclusion

All of the stated grounds of rejection have been properly traversed. Applicants respectfully request that the Examiner reconsider and withdraw all of the presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment is respectfully requested.

Respectfully submitted,

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